EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Tina and Kenneth Morrow v. Ethicon, Inc., et al.* *Case No. 2:12-cv-00378*	

RULE 26 EXPERT REPORT OF NATHAN W. GOODYEAR, MD

BACKGROUND

I received my Bachelor of Arts from Louisiana Tech University in Ruston, LA and Doctor of Medicine from LSU Health Sciences Center in Shreveport, LA. I am Board Certified in Obstetrics and Gynecology and was the Chief Resident in Obstetrics/Gynecology at the University of Tennessee in Knoxville. While at the University of Tennessee, I specialized in minimally-invasive vaginal and pelvic floor surgery and was recognized and awarded the top pelvic floor surgeon in my graduating residency class. I practiced 2 years (2004-2006) in Columbus, GA and 7 years in Ruston, LA (2006-2013). My 9 years of Obstetrics and Gynecology practice focused on minimally-invasive vaginal surgery and pelvic floor reconstruction. I performed in excess of 300 procedures: including abdominal sacral colpopexy, anterior Prolift, anterior colporrhaphy, lateral vaginal wall repair, posterior Prolift, posterior colporrhaphy, total Prolift, TVT (TVT, TVT-O, TVT-S), mesh revision, partial colpocleisis, and complete colectomy for patients with pelvic floor problems during clinical practice from 2004-2009. Approximately, greater than 50% of repair procedures involved the use of mesh (Gynemesh, total Prolift, anterior Prolift, posterior Prolift, TVT, TVT-O, TVT-S). In addition, in

excess of 100 procedures: including abdominal sacral colpopexy, anterior colporrhaphy, posterior colporrhaphy, vaginal Gynemesh placement, lateral vaginal wall repair, TVT (TVT, TVT-O), partial colpocleisis, and complete colectomy were performed during my OB/GYN residency from 2000-2004. These procedures in my OB/GYN residency and clinical practice included surgical repair of uterine prolapse, vaginal vault prolapse, cystocele, lateral vaginal wall defects, enterocele, rectocele, mesh revision, and stress urinary incontinence. Currently, while still seeing gynecological patients, I am a Fellowship-Trained Metabolic Specialist and I predominantly practice metabolic medicine in Knoxville, TN.

See CV attached as Exhibit 1

See list of materials considered in rendering my opinions, attached as Exhibit 2.

In the last 4 years, I have not testified as an expert at trial or deposition. Compensation was paid at $500/hour for preparation of report.

CLINICAL SUMMARY

The patient first presented on 6.11.08 for menopausal symptoms and hypothyroidism. A stage II cystocele, rectocele, and enterocoele were found on examination. Pertinent surgical history included hysterectomy ('92), bilateral oophorectomy with lysis of adhesions ('94), and lumbar discectomy ('11). Pertinent history included hypothyroidism and depression. Urodynamic evaluation revealed mixed urinary incontinence. A total Profit and TVT-O was performed on 8.12.08 for cystocele and rectocele repair without complications. Vaginal Estradiol cream was prescribed immediately post-operative.

At 6 weeks post-op (9.22.08), a small piece of mesh or less likely suture was noted anteriorly on exam. The small area was excised in office without residual mesh or suture noted on exam. The 6 week post-op period was remarkable only for pelvic/groin pain and normal bloody vaginal discharge. Continued pelvic rest was recommended.

The patient presented on 10.6.08 with complaints of increased blood discharge and vaginal bleeding with bowel movements. The patient had also noted an increase in vaginal odor accompanying the discharge. A more obvious exposure was visualized proximal, anteriorly and posteriorly at the level of the posterior fourchette. The patient was scheduled for excision of the vaginal mesh exposures.

The first vaginal mesh exposure excision occurred on 10.14.08. An approximately 1x1 cm anterior exposure was removed anteriorly and a smaller exposure posteriorly was removed. Post-operatively, the pain and bleeding persisted. Colace and vaginal estrogen were continued

post-operatively. The patient was cleared at 6 weeks post-op. No mesh was seen or palpated vaginally on post-op exam. The patient underwent 6 weeks of pelvic floor therapy.

The patient presented on 1.30.09 with continued vaginal bleeding, pelvic pain, and painful intercourse. The patient's husband complained of "rough areas during intercourse". This persistent discomfort during intercourse had led to the cessation of sexual relations. Pelvic exam revealed no vaginal mesh erosion.

The patient presented to Dr Bobby Ensminger for post-menopausal vaginal bleeding. The patient was referred to Dr Landon Smith. An additional posterior vaginal mesh exposure was found by Dr Landon Smith on 11.13.09. She was referred to Southeast Urogynecology for additional follow up. A CT of the pelvis was negative and a cystoscopy was also negative.

Small, anterior mesh erosion and posterior, distal mesh erosions were visualized by Dr Robert Harris on 1.26.10. A second posterior vaginal mesh exposure excision was performed on 4.7.10 by Dr Robert Harris. The pathology report revealed "fibrous tissue" consistent with chronic inflammation. An erosion was noted at the 8 week post-op visit (6.2.10) by Dr Robert Harris. Vaginal granulation tissue was also noted on the 8 week post-op examination. The patient currently has a 3rd surgical mesh excision with transection of the mesh arms planned. As of the date of the writing of this report, I have not seen the operative report from this procedure.

Tina Morrow presented to Dr Niall Galloway at the Emory Clinic, Department of Urology, on 11.6.2015 for evaluation. Tina Morrow complained of daily vaginal bleeding, recurrent UTI's, urinary urgency, urinary incontinence, pain that limited ability to even perform daily tasks i.e. picking up kids, going to work, exercise, mopping floors, shopping, gardening… The pain was described as worse with exercise, prolong walking, cleaning, bending over, pulling, lifting and improved only with sitting in a recliner and with the use of daily tramadol. Tina Morrow said she was "scared for my husband" and scared of "relations". Tina Morrow, per Dr Galloway's notes, described herself as "half a woman" and said she feels "like mesh is growing out of my face". Examination by Dr Niall Galloway revealed "urethral hypermobility", "exposed vaginal mesh" on the "anterior wall". Dr Galloway also referred to this finding as a "transverse band of mesh". The "left side" was worse according to Dr Galloway's assessment. Physical exam also found "tight arms" on right, but not the left and tenderness over the rectum.

See my notes from my most recent exam on 11.19.15. Records attached as Exhibit 3.

Vaginal bleeding, vaginal discharge with odor, pelvic and groin pain, and burning in the groin area were persistent from the initial placement of the mesh products. The intensity of the pain has progressively increased since the placement of the mesh products. The pain is described as a constant dull pain with episodes of sharp pains that can be of high intensity. Exercise has

become impossible due to the pelvic pains. The patient even describes walking as painful. Simple working around the house, yard that requires any bending and/or equating is intolerable due to pain.

The patient also complains of chronic urinary tract infections (UTI) since the placement of the mesh products. Persistent vaginal bleeding with bowel movements has increased since the placement of the mesh products. Rheumatoid arthritis was diagnosed 3 years after placement of the mesh products. Tina Morrow feels as she is "half a women" as a result of the placement of the mesh products. Marital stress has resulted from the cessation of sexual relations due to the associated pelvic pain.

METHODOLOGY

For my opinions rendered in this report, I have relied upon my training, experience and education as a Board Certified Gynecologist and Obstetrician. I have also relied on my personal experience and personal knowledge of the products subject to this litigation. Additionally, I have reviewed the list of materials attached to the end of this report, some provided by counsel, and some either in my possession or procured by me personally.

I made a differential of the possible causes of Tina Morrow's post-operative issues and their relationship to the mesh implants, if any.

For **vaginal discharge**, the differential includes:

1. persistent vaginal foreign body erosion
2. atrophic vaginitis
3. infectious vaginitis
4. fistula
5. chronic inflammation secondary to foreign body
6. granulation tissue

For **dyspareunia (painful intercourse)**, the differential includes:

1. persistent vaginal foreign body erosion
2. contracted vaginal mesh
3. atrophic vaginitis
4. granulation tissue
5. post-op scarring

For **pelvic pain**, the differential includes:

1. persistent vaginal foreign body erosion
2. contracted vaginal mesh
3. chronic inflammation secondary to foreign body
4. granulation tissue
4. fistula
5. post-op scarring

For **vaginal bleeding**, the differential includes:

1. persistent vaginal foreign body erosion
2. atrophic vaginitis
3. infectious vaginitis
4. fistula
5. chronic inflammation secondary to foreign body
6. granulation tissue

A foreign body reaction in the vagina can be from any material, iatrogenic or otherwise, left and/or exposed later in the vagina.

After considering these differentials, mesh erosion, exposure, extrusion, contraction, scarring, hardening and/or banding, as a cause of the patient's condition(s) were considered. Taking into account her pelvic exam findings, symptoms, scientific literature and my training and experience, I came to my conclusions regarding the nature and cause of TINA MORROW's conditions.

Next, I applied the information provided to physicians, including myself, regarding risks of mesh usage, particularly for the transvaginal repair of pelvic organ prolapse and stress urinary incontinence. I also applied information contained in the materials provided to physicians, including myself, to distribute to patients in the office.

OPINIONS

All opinions are given to a reasonable degree of medical probability.

1) TINA MORROW's injuries were caused by the implanted Prolift and TVT-O devices.

Complications from the Prolift include: bleeding, including hemorrhage and/or hematoma; urinary incontinence; urge incontinence; urinary frequency; urinary retention or obstruction; voiding dysfunction; acute and/or chronic pain; wound dehiscence; nerve damage; recurrent prolapse; inflammation; adhesion formation; fistula formation; contracture; scarring; mesh extrusion/exposure/erosion into the vagina or other structures or organs; pelvic pain; pain with intercourse; cessation of sexual activities, excessive contraction or shrinkage leading to vaginal scarring, tightening and/or shortening; infection; infection potentiation; neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area; seroma; adhesion formation; atypical vaginal discharge; mesh exposure causing pain or discomfort to sexual partners during intercourse; significant dissection in the event of removal. Such complications have been reported in peer-reviewed medical literature, and have been observed by me in my own practice.

Complications from the TVT-O include: post-operative bleeding; punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, and may require surgical repair; transitory local irritation at the wound site; foreign body response resulting in extrusion, erosion, exposure, fistula formation and/or inflammation; existing infection potentiation; mesh extrusion, exposure, or erosion into the vagina or other structures or organs; infection; temporary or permanent lower urinary tract obstruction; acute and or chronic pain; voiding dysfunction; pain with intercourse, which may be permanent; neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg pelvic and/or abdominal area;

recurrence of incontinence; bleeding, including hemorrhage, or hematoma; one or more revision surgeries to treat adverse reactions; significant dissection in the event removal becomes necessary with associated risk of nerve and organ inury; seroma; urge incontinence; urinary frequency; urinary retention; adhesion formation; atypical vaginal discharge; mesh exposure causing pain or discomfort to sexual partners during intercourse. These complications have been reported in peer-reviewed medical literature, and have been observed by me in my own practice.

Tina Morrow suffered injuries, including the pelvic pain, vaginal mesh erosions, repeated vaginal surgical erosion excisions, repeated UTI infections, persistent vaginal bleeding, the continuous vaginal discharge with odor, significant dyspareunia that has resulted in cessation of sexual relations and the associated marital stress that has resulted, emotional distress and anxiety, and the significant decline in quality of life. These injuries were caused by the Prolift, and TVT-O, and are directly related to their flawed design. There is no evidence of surgical error in the implantation of the Prolift or TVT-O, which were performed according to the medically accepted methods as taught to me in sessions I attended that were put on by the manufacturer, and my own training and experience having performed in excess of 300 procedures. The mesh manufacturer knew or should have known, and should have advised clinicians and patients of the complications and medical treatment required to treat these complications. Care and treatment for the complications following implantation was indicated and met the standard of care. Tina Morrow, more likely than not, will need continued treatment, including surgical resection of probable future mesh exposures, the continued pelvic and groin pain, biofeedback for urinary urgency and urinary retention, periodic antibiotics for recurrent urinary tract infections, treatment for chronic vaginal bleeding, treatment for the chronic vaginal discharge with odor, management of permanent injury resultant from the initial Prolift and TVT-O placement and the repeated excisions and debridement of mesh exposures, treatment for increased obesity and associated increased risk of chronic diseases of aging resultant from decreased mobility and ability to exercise, and counseling for psychological impact of chronic pelvic pain, painful intercourse resultant in cessation of sexual activities and the impact on present relationships as my notes reflect.

Safer alternatives were available that are equally effective. If Mrs. Morrow had undergone an alternative procedure, she, more likely than not, would not have suffered the above-listed injuries.

2) The Prolift and TVT-O devices implanted in Tina Morrow were unreasonably dangerous due to the lack of adequate warning.

The injuries experienced by Tina Morrow, which were caused by the Prolift and TVT-O devices, i.e. pelvic pain, vaginal mesh erosions, repeated vaginal surgical erosion excisions,

repeated UTI infections, persistent vaginal bleeding, the continuous vaginal discharge with odor, significant dyspareunia that has resulted in cessation of sexual relations and the associated marital stress that has resulted, emotional distress and anxiety, and the significant decline in quality of life, were not adequately described in the directions for use.

For example, the Prolift directions for use indicate the potential for "transient leg pain may occur and can usually be managed with mild analgesics." Also, for example, with the TVT-O, the directions for use do not warn about the potential for acute or chronic neuromuscular pelvic pain. Neither product's directions for use make any mention of chronic pelvic pain, chronic dyspareunia, persistent vaginal bleeding, such as that experienced by Mrs. Morrow.

Where injuries such as those experienced by Mrs. Morrow are referenced, for instance, infection and erosion, were identified in the directions for use, the information provided was inadequate regarding severity, frequency and responsiveness to treatment. In addition, inadequate warning about the mesh chronic foreign body reaction potential, mesh contracture/ shrinkage, mesh fraying and mesh roping/banding was provided. The directions for use also do not adequately warn or describe how physicians are to treat patients who experience complications from these products. For instance, surgical removal of the Prolift can be difficult and risky. It is virtually impossible to remove in its entirety. Often, complications caused by the mesh require multiple surgical interventions. The warnings provided in the directions for use failed to describe the invasive nature of surgical procedures necessary to treat these complications, including the potential for further injury.

3) The Prolift and TVT-O implanted in Tina Morrow were unreasonably dangerous because they did not conform to the manufacturer's express warranties.

Additionally, Ethicon provided me with materials regarding the Prolift and TVT-O devices, which included, directions for use and marketing materials intended to be displayed in my office and shared with patients, including Mrs. Morrow. In these materials, Ethicon and Johnson & Johnson made certain express warranties about the Prolift and TVT-O. For example, the Prolift patient brochures specifically warranted that:

(a) The Prolift mesh was "soft;"

(b) The Prolift allowed for "the restoration of sexual function by restoring normal vaginal anatomy;"

(c) "Many patients return to normal daily activities within three to four days. Most completely recover within a two to three week period;"

(d) Risks are "rare" and "small;"

(e) The Prolift is appropriate for almost all patients including patients who are overweight, elderly or have undergone previous surgeries for pelvic organ prolapse.

Similarly, for example, the Prolift directions for use warranted that:

(a) The mesh "elicits a minimum to slight inflammatory reaction, which is transient;"

(b) The mesh "remains soft and pliable;"

(c) "normal wound healing is not noticeably impaired."

Likewise, the TVT-O patient brochures warranted:

(a) The TVT-O required a "short recovery period" and a "quick return to normal activities"

(c) The TVT-O was proven clinically safe

(d) Today's "minimally invasive procedures" are "safe"

(e) "few patients experienced complications"

(f) little discomfort occurs after the procedure

g) overstated the benefits of the TVT-O

h) understated the risks of the TVT-O

Similarly, for example, the TVT-O directions for use warranted that:

(a) The mesh "elicits a minimal inflammatory reaction in tissues, which is transient;"

(b) The mesh is incorporated into the adjacent tissue

(c) The PROLENE polypropylene mesh "has been reported to be non-reactive"

(d) Local irritation at the surgical site is "transitory"

(e) The foreign body response is "transitory"

These are but a few examples of the many warranties offered by the manufacturer of the Prolift and the TVT-O devices, which, based upon my experience, both implanting transvaginal

mesh devices, urethral suspension devices and performing mesh revision procedures, were either false or misleading or both. These warranties are also further examples of the inadequacy of the warnings given about these products.

CONCLUSION

It is my opinion that the above-listed, unreasonably dangerous characteristics of the Prolift and TVT-O products implanted in TINA MORROW caused her pelvic pain, vaginal mesh erosions, repeated vaginal surgical erosion excisions, repeated UTI infections, persistent vaginal bleeding, the continuous vaginal discharge with odor, significant dyspareunia that has resulted in cessation of sexual relations and the associated marital stress that has resulted, emotional distress and anxiety, and the significant decline in quality of life. I reserve the right to supplement my report as new information is made available or new issues are raised.

Dated February 1, 2016.

NATHAN W. GOODYEAR, MD
10607 Deer Brook Drive
Knoxville, Tennessee 37922
Telephone: (865) 675-9355

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327** **JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Tina and Kenneth Morrow v. Ethicon, Inc., et al.* *Case No. 2:12-cv-00378*	

RULE 26 SUPPLEMENTAL EXPERT REPORT OF NATHAN W. GOODYEAR, MD

BACKGROUND

I received my Bachelor of Arts from Louisiana Tech University in Ruston, LA and Doctor of Medicine from LSU Health Sciences Center in Shreveport, LA. I am Board Certified in Obstetrics and Gynecology and was the Chief Resident in Obstetrics/Gynecology at the University of Tennessee in Knoxville. While at the University of Tennessee, I specialized in minimally-invasive vaginal and pelvic floor surgery and was recognized and awarded the top pelvic floor surgeon in my graduating residency class. I practiced 2 years (2004-2006) in Columbus, GA and 7 years in Ruston, LA (2006-2013). My 9 years of Obstetrics and Gynecology practice focused on minimally-invasive vaginal surgery and pelvic floor reconstruction. I performed in excess of 300 procedures; including abdominal sacral colpopexy, anterior Prolift, anterior colporrhaphy, lateral vaginal wall repair, posterior Prolift, posterior colporrhaphy, total Prolift, TVT (TVT, TVT-O, TVT-S), mesh revision, partial colpocleisis, and complete colectomy for patients with pelvic floor problems during clinical practice from 2004-2009. Approximately, greater than 50% of repair procedures involved the use of mesh (Gynemesh, total Prolift, anterior Prolift, posterior Prolift, TVT, TVT-O, TVT-S). In addition, in

excess of 100 procedures: including abdominal sacral colpopexy, anterior colporrhaphy, posterior colporrhaphy, vaginal Gynemesh placement, lateral vaginal wall repair, TVT (TVT, TVT-O), partial colpocleisis, and complete colectomy were performed during my OB/GYN residency from 2000-2004. These procedures in my OB/GYN residency and clinical practice included surgical repair of uterine prolapse, vaginal vault prolapse, cystocele, lateral vaginal wall defects, enterocele, rectocele, mesh revision, and stress urinary incontinence. Currently, while still seeing gynecological patients, I am a Fellowship-Trained Metabolic Specialist and I predominantly practice metabolic medicine in Knoxville, TN.

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In the last 4 years, I have not testified as an expert at trial or deposition. Compensation was paid at $500/hour for preparation of report.

CLINICAL SUMMARY

The patient first presented on 6.11.08 for menopausal symptoms and hypothyroidism. A stage II cystocele, rectocele, and enterocoele were found on examination. Pertinent surgical history included hysterectomy for uterine prolapse ('92), bilateral oophorectomy with lysis of adhesions ('94), and lumbar discectomy ('11). Pertinent history included hypothyroidism and depression. Urodynamic evaluation revealed mixed urinary incontinence. A total Profit and TVT-O was performed on 8.12.08 for cystocele and rectocele repair without complications. Vaginal Estradiol cream was prescribed immediately post-operative.

At 6 weeks post-op (9.22.08), a small piece of mesh or less likely suture was noted anteriorly on exam. The small area was excised in office without residual mesh or suture noted on exam. The 6 week post-op period was remarkable only for pelvic/groan pain and normal bloody vaginal discharge. Continued pelvic rest was recommended.

The patient presented on 10.6.08 with complaints of increased blood discharge and vaginal bleeding with bowel movements. The patient had also noted an increase in vaginal odor accompanying the discharge. A more obvious exposure was visualized proximal, anteriorly and posteriorly at the level of the posterior fourchette. The patient was scheduled for excision of the vaginal mesh exposures.

The first vaginal mesh exposure excision occurred on 10 14 08 An approximately 1x1 cm anterior exposure was removed anteriorly and a smaller exposure posteriorly was removed. Post-operatively, the pain and bleeding persisted. Colace and vaginal estrogen were continued

post-operatively. The patient was cleared at 6 weeks post-op. No mesh was vaginal on post-op exam. The patient underwent 6 weeks of pelvic floor therapy.

The patient presented on 1.30.09 with continued vaginal bleeding pelvic pain, painful intercourse. The patient's husband complained of "rough areas during intercourse" persistent discomfort during intercourse had led to the cessation of sexual Pelvic revealed no vaginal mesh erosion.

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See my notes from my most recent exam on 11/19/15. Records attached as Exhibit

Tina Morrow was seen by Dr. Winters o . . and posterior vaginal mesh exposure. A culture positive urinary tract infection (>1

coli) was diagnosed and treated. Tina Morrow was seen on 3.29.2016 for a preoperativ cystourethroscopy for bladder clearance. A urinary tract infection was again diagnosed and treated. Surgical removal of the exposed anterior and posterior vaginal mesh was success performed on 3.30.2016. Intraoperatively, Dr Winters noted "a plate of mesh extending from th arms distally to the distal vagina near the perineal body" posteriorly and "an extensive degree of fibrosis and scarring" posteriorly that made the dissection "difficult". Dr. Winters also noted the mesh attachment posteriorly to the pelvic sidewall bilaterally creating a "retraction of the mes " Anteriorly, a "plate of mesh" was noted on dissection. Attachment of the anterior mesh to the pelvic side wall was also noted. Pathologic specimen included "pinkish maroon fragments soft tissue with underlying adhered mesh-like material". Tina Morrow tolerated the surgery well and was discharged home after 23 hours observation.

Vaginal bleeding, vaginal discharge with odor, pelvic and groin pain, and burning in th groin area were persistent from the initial placement of the mesh products. The intensity of the pain has progressively increased since the placement of the mesh products. The pain is des as a constant dull pain with episodes of sharp pains that can be of high intensity. Exercise has become impossible due to the pelvic pains. The patient even describes walking as painful Simple working around the house, yard that requires any bending and/or equating is intolerab due to pain.

The patient also complains of chronic urinary tract infections (UTI) since the placement of the mesh products. Persistent vaginal bleeding with bowel movements has increased since the placement of the mesh products. Rheumatoid arthritis was diagnosed 3 years after placement o the mesh products. Tina Morrow feels as she is "half a women" as a result of the placement of the mesh products. Marital stress has resulted from the cessation of sexual relations due to the associated pelvic pain.

METHODOLOGY

For my opinions rendered in this report, I have relied upon my training, experience and education as a Board Certified Gynecologist and Obstetrician. I have also relied on my persona experience and personal knowledge of the products subject to this litigation. Additionally, I have reviewed the list of materials attached to the end of this report, some provided by counsel, some either in my possession or procured by me personally.

I made a differential of the possible causes of Tina Morrow's post-operative issues and their relationship to the mesh implants, if any.

For **vaginal discharge**, the differential includes:

1. persistent vaginal foreign body erosion
2. atrophic vaginitis
3. infectious vaginitis
4. fistula
5. chronic inflammation secondary to foreign body
6. granulation tissue

For **dyspareunia (painful intercourse)**, the differential includes:

1. persistent vaginal foreign body erosion
2. contracted vaginal mesh
3. atrophic vaginitis
4. granulation tissue
5. post-op scarring

For **pelvic pain**, the differential includes:

1. persistent vaginal foreign body erosion
2. contracted vaginal mesh
3. chronic inflammation secondary to foreign body
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For **vaginal bleeding**, the differential includes:

1. persistent vaginal foreign body erosion

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A foreign body reaction in the vagina can be from any material, iatrogenic or otherwise, left and/or exposed later in the vagina.

After considering these differentials, mesh erosion, exposure, extrusion, contraction, scarring, hardening and/or banding, as a cause of the patient's condition(s) were considered. Taking into account her pelvic exam findings, symptoms, scientific literature and my training and experience, I came to my conclusions regarding the nature and cause of TINA MORROW's conditions.

Next, I applied the information provided to physicians, including myself, regarding risks of mesh usage, particularly for the transvaginal repair of pelvic organ prolapse and stress urinary incontinence. I also applied information contained in the materials provided to physicians, including myself, to distribute to patients in the office.

OPINIONS

All opinions are given to a reasonable degree of medical probability.

1) TINA MORROW's injuries, including her most recent revision surgery, performed by Dr. Winters on March 30, 2016, were caused by the implanted Prolift and TVT-O devices.

Complications from the Prolift include: bleeding including hemorrhage and/or hematoma; urinary incontinence; urge incontinence; urinary frequency, urinary retention or obstruction; voiding dysfunction; acute and/or chronic pain; wound dehiscence; nerve damage; recurrent prolapse; inflammation; adhesion formation; fistula formation; contracture; fibrosis and

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Safer alternatives were available that are equally effective. If Mrs. Morrow had undergone an alternative procedure, she, more likely than not, would not have suffere above-listed injuries.

2) The Prolift and TVT-O devices implanted in Tina Morrow were unreasonabl dangerous due to the lack of adequate warning.

The injuries experienced by Tina Morrow, which were caused by the Prolift and TVT-O devices, i.e. pelvic pain, mesh plate formation, mesh retraction, vaginal mesh erosions, repeate vaginal surgical erosion excisions, repeated UTI infections, persistent vaginal bleeding, the continuous vaginal discharge with odor, significant dyspareunia that has resulted in cessati sexual relations and the associated marital stress that has resulted, emotional distress and and the significant decline in quality of life, were not adequately described in the directions for use.

For example, the Prolift directions for use indicate the potential for "transient leg may occur and can usually be managed with mild analgesics." Also, for example, with the TVT O, the directions for use do not warn about the potential for acute or chronic neuromusc pelvic pain. Neither product's directions for use make any mention of chronic pelvic pain, chronic dyspareunia, persistent vaginal bleeding, such as that experienced by Mrs. Morro .

Where injuries such as those experienced by Mrs. Morrow are referenced, for instance infection and erosion, were identified in the directions for use, the information provided was inadequate regarding severity, frequency and responsiveness to treatment. The directions for use do not adequately warn or describe how physicians are to treat patients who experien complications from this product. For instance, surgical removal of the Prolift can be difficult risky. It is virtually impossible to remove in its entirety In addition, inadequate warning about the mesh chronic foreign body reaction potential, mesh plate formation, fibrosis and sc mesh contracture/shrinkage, mesh fraying, mesh degradation and mesh roping/banding was

provided. Often, complications caused by the mesh require multiple surgical interventions. The warnings provided in the directions for use failed to describe the invasive nature of surgical procedures necessary to treat these complications, including the potential for further injury.

3) The Prolift and TVT-O implanted in Tina Morrow were unreasonably dangerous because they did not conform to the manufacturer's express warranties.

Additionally, Ethicon provided me with materials regarding the Prolift and TVT-O devices, which included, directions for use and marketing materials intended to be displayed in my office and shared with patients, including Mrs. Morrow. In these materials, Ethicon and Johnson & Johnson made certain express warranties about the Prolift and TVT-O. For example, the Prolift patient brochures specifically warranted that:

(a) The Prolift mesh was "soft;"

(b) The Prolift allowed for "the restoration of sexual function by restoring normal vaginal anatomy;"

(c) "Many patients return to normal daily activities within three to four days. Most completely recover within a two to three week period;"

(d) Risks are "rare" and "small;"

(e) The Prolift is appropriate for almost all patients including patients who are overweight, elderly or have undergone previous surgeries for pelvic organ prolapse.

Similarly, for example, the Prolift directions for use warranted that:

(a) The mesh "elicits a minimum to slight inflammatory reaction, which is transient;"

(b) The mesh "remains soft and pliable;"

(c) "normal wound healing is not noticeably impaired."

Likewise, the TVT-O patient brochures warranted:

(a) The TVT-O required a "short recovery period" and a "quick return to normal activities"

(c) The TVT-O was proven clinically safe

(d) Today's "minimally invasive procedures" are "safe"

(e) "few patients experienced complications"

(f) little discomfort occurs after the procedure

g) overstated the benefits of the TVT-O

h) understated the risks of the TVT-O

Similarly, for example, the TVT-O directions for use warranted that:

(a) The mesh "elicits a minimal inflammatory reaction in tissues, which is transient;"

(b) The mesh is incorporated into the adjacent tissue

(c) The PROLENE polypropylene mesh "has been reported to be non-reactive"

(d) Local irritation at the surgical site is "transitory"

(e) The foreign body response is "transitory"

These are but a few examples of the many warranties offered by the manufacturer of the Prolift and the TVT-O devices, which, based upon my experience, both implanting transvaginal mesh devices, urethral suspension devices and performing mesh revision procedures, were either false or misleading or both. These warranties are also further examples of the inadequacy of the warnings given about these products.

CONCLUSION

It is my opinion that the above-listed, unreasonably dangerous characteristics of the Prolift and TVT-O products implanted in TINA MORROW caused her pelvic pain, vaginal mesh erosions, repeated vaginal erosions, surgical excisions and removal, including the March 30, 2016 revision procedure, repeated UTI infections, persistent vaginal bleeding, the continuous vaginal discharge with odor, significant dyspareunia that has resulted in cessation of sexual relations and the associated marital stress that has resulted, emotional distress and anxiety, and the significant decline in quality of life. I reserve the right to supplement my report as new information is made available or new issues are raised.

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